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TITLE: Improving Quality of Life in Ovarian Cancer Patients: A

Brief Intervention for Patients and their Partners

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The current study examines the effects of a psychological intervention that encourages emotional expression in ovarian cancer patients and their partners. Ovarian cancer patients (n=130) and their partners are randomly assigned to an intervention or a control group. Following Pennebaker's model, subjects in the intervention group are asked to write about their deepest thoughts and feelings regarding their cancer experience for 20 minutes each day for three consecutive days. The control group is asked to write about trivial nonemotional topics. Outcome variables including psychological distress, quality of life, and physical symptoms are assessed at baseline and over a period of nine months after the intervention (one week, three, six, and nine months).

In accordance with our approved Statement of Work data collection is currently underway. To date 27 subjects have been enrolled and are at various stages of the data collection process. Data processing is continuing as planed, including data entry and verification, which has been completed for all subjects currently enrolled in the project.

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Introduction

The current study examines the effects of a psychological intervention that encourages emotional expression in ovarian cancer patients and their partners. Ovarian cancer patients (n=130) and their partners are recruited at Chicago area hospitals. Eligibility of patients includes ability to read and write in English, absence of any concurrent chronic condition or concurrent or prior history of psychiatric disorders, and having a spouse or partner. Patients are recruited between two months to five years after diagnosis, and after completion of active cancer treatment (e.g., surgery, radiation). They are also asked for permission to contact their spouse or partner for recruitment into the study. As it is our goal to recruit a partner for each patient to maximize effectiveness of the intervention, the only exclusion criteria for patients' partners will be inability to read and write in English or any psychiatric disorder that would preclude participation. Patients and their partners are randomly assigned to an intervention or a control group. Subjects in the intervention group are asked to write about their deepest thoughts and feelings regarding their cancer experience for 20 minutes each day for three consecutive days. The control group is asked to write about trivial non-emotional topics. Intervention Group: Subjects are told to write continuously for 20 minutes about their deepest thoughts and feelings about their cancer experience (spouses/partners will write about how they have been affected by the patient's illness), and about how it relates to other aspects of their lives, e.g., their family life, relationship with their spouse, sexuality, daily activities, work, social life, etc. The instructions are designed such that subjects will feel free to write about the aspects of their experience that are important to them. encourage emotional expression, it is emphasized that their writing samples will be kept completely confidential and anonymous and will only be identified by the participant's number, not their name. The essays will later be processed by independent blind readers who have no knowledge of the participant's identity or group assignment. Finally, participants are told to not worry about style, grammar, or spelling and that no feedback will be provided to them regarding the contents of the essays. Control Group: Procedures follow standard protocols used in previous research. Subjects are asked to write for 20 minutes each day about a trivial non-emotional topic that is assigned to them (e.g., description of their routine daily activities). Subjects will be told to remain factual and not add any emotional content. All other procedures will be identical to the Intervention Group.

Outcome variables including psychological distress, quality of life, and physical symptoms are assessed at baseline and over a period of nine months after the intervention (one week, three, six, and nine months).

Specific Aim I: To examine the effectiveness of the emotional writing intervention for patients and their partners. Specific Aim II: To examine mechanisms for the effects of expressive writing. Specific Aim III: To begin to identify those individuals who will be most likely to benefit from this type of intervention.

Body

Task 1: Preparation for the study (month 1 to 2):

The research protocols have been developed including instructions for all aspects of the protocol and questionnaire packets for each assessment. Research assistants have been trained to administer all parts of the protocol including the intervention, all assessments, and debriefings.

Task 2: Data collection (month 2 to 36):

Collaborating physicians are referring research subjects on an ongoing basis. Currently a total of 27 subjects have been recruited into the protocol and are at various stages of the data collection process. We are continuing to receive referrals from our collaborators and are screening and recruiting subjects on a regular basis. Interviews and interventions are being conducted by the research assistants and follow-up assessments are done at one week, 3, 6, and 9 months post-intervention as planned. We are keeping track of recruitment and subject follow-up using a computerized database (ongoing). Weekly research meetings are in place to deal with the day to day running of the project.

Task 3: Data processing (month 6 to 36):

Data spreadsheets have been set up and all data currently collected have been entered. Data verification is conducted periodically to ensure accuracy of data processing.

Task 4: Data analyses (month 34-36):

Data analyses will begin at month 34 as planned therefore no results are available yet. Data analyses would not be informative at this stage of the research process.

Please note: Due to a considerable delay (5 months) in approval by the DOD human subjects protection office we were unable to begin our study until February of 2002.

Key Research Accomplishments

- Research protocol and referral mechanisms are in place and continue to run as planned.
- A total of 27 subjects are enrolled in the study.
- Additional referrals are being obtained on an ongoing basis and patients are being screened for eligibility.
- Data entry and verification is conducted on an ongoing basis.
- Weekly research meetings are conducted.

Reportable Outcomes

No reportable outcomes are available so far. This is in line with expectations delineated in our Statement of Work.

Conclusions

The research protocol is running as planned and no modifications are necessary at this point.